UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, Plaintiff, -against- NOVARTIS PHARMACEUTICALS CORPORATION, Defendant.	**11 CIV. 8196 (CM)**

NOVARTIS PHARMACEUTICALS CORPORATION'S MEMORANDUM OF LAW IN SUPPORT OF ITS RULE 12(B)(6) MOTION TO DISMISS THE AMENDED COMPLAINT IN INTERVENTION OF THE UNITED STATES OF AMERICA

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Consistent with the Court's May 29, 2014 Memorandum Decision and Order (Dkt. No. 192) ("Novartis I"), Defendant Novartis Pharmaceuticals Corporation ("NPC") submits this Memorandum of Law in support of its motion to dismiss, pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure, the Amended Complaint in Intervention ("Amended Complaint") filed by the United States of America. (The United States of America is referred to collectively with the intervening states as the "Government", and the arguments made below apply with equal force to the complaints filed by the various states.)

PRELIMINARY STATEMENT

This brief addresses the legal question raised by the Court in Novartis I: Whether to maintain a claim under the False Claims Act ("FCA"), 31 U.S.C. § 3729, the Government is required to plead at least some causal nexus between (i) the alleged kickbacks NPC purportedly paid to specialty pharmacies to influence improperly the prescribing decisions of physicians; and (ii) the actual prescribing decisions of those physicians, which resulted in claims for reimbursement that the Government now challenges as "false". NPC respectfully submits that in keeping with the plain language and intent of the FCA and the Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(g), and relevant case law, the Government must plead a nexus (and it must do so with particularity).

The Government argues that it is not required to allege any causal nexus. Under the Government's theory, it need only plead that NPC paid kickbacks to specialty pharmacies in connection with the NPC drugs Exjade and Myfortic. Once such kickbacks are alleged, the Government contends, every single claim submitted by the specialty pharmacy thereafter for reimbursement of an Exjade or Myfortic prescription is "legally false", regardless of whether the pharmacist influenced the prescribing physician to make a clinically inappropriate treatment

decision—or even spoke to the prescribing physician at all. In the case of Exjade, the Government claims NPC paid kickbacks to BioScrip (a specialty pharmacy) and, in exchange, BioScrip agreed to contact patients and convince them to order refills of existing Exjade prescriptions that were somehow "not needed or clinically appropriate". As pleaded, the Government's case encompasses claims associated with Exjade patients who refilled their existing, valid prescriptions without any contact at all from BioScrip; it even encompasses claims for the initial dispensing of Exjade pursuant to a doctor's prescription—claims that do not appear to be part of the alleged Exjade "refill" scheme.

As set forth below, the Government's theory is wrong.

First, the AKS explicitly provides that a claim submitted to the government for reimbursement is "false or fraudulent" for purposes of the FCA where the claim "includes items or services resulting from a violation" of the AKS. 42 U.S.C. § 1320a-7b(g) (emphasis added). The "items and services" at issue here are prescriptions for Exjade and Myfortic; the alleged AKS violations are purported kickback payments made by NPC to specialty pharmacies. NPC submits that the only way for the relevant items (Exjade and Myfortic prescriptions) to "result from" the alleged kickback payments to specialty pharmacies is for the pharmacist improperly to influence the physician's decision to prescribe Myfortic and the patient's decision to refill his or her Exjade prescription (where that refill is somehow not necessary or clinically inappropriate). Accordingly, unless the Government alleges that a physician prescribed Myfortic based on an improper recommendation by a specialty pharmacy, or that a patient improperly ordered an Exjade refill because of communications with BioScrip, the claims for those prescriptions that it challenges should not be deemed "false claims" under the FCA. (See infra Part I.A.)

Second, requiring a "but for" nexus between the alleged kickback scheme and the prescribing decision is consistent with the stated purpose and intent of both the AKS and FCA. The AKS is meant to ensure that a physician's medical judgment is based on the best interests of the patient, and not improper financial incentives. The FCA was enacted to "indemnify the government . . . against losses caused by a defendant's fraud". Mikes v. Strauss, 274 F.3d 687, 696 (2d Cir. 2001). Where a physician prescribes Exjade or Myfortic based on his or her own medical judgment, and not due to any supposed improper influence by a pharmacist, neither statute is implicated: the physician's judgment is not "compromised by improper financial incentives", nor is there any "loss" to the government. (See infra Part I.B.)

Third, NPC is unable to find a single case in the healthcare context where an FCA action against a pharmaceutical manufacturer for causing false prescription drug claims to be submitted to the government was upheld absent some allegation that the fraudulent scheme improperly influenced the medical judgment of the prescriber. The cases cited by the Government as support for its "no nexus" theory similarly include allegations that a physician's medical judgment was influenced, most typically that the physician himself or herself received a kickback. Permitting the Government to state an FCA violation in the healthcare context without requiring it to identify how—or even if—the medical treatment decision was implicated would be a significant (and unwarranted) departure from prior precedent. (See infra Part I.C.)

* * *

For these reasons, NPC respectfully urges this Court to reject the Government's theory of falsity, which is inconsistent with relevant law and potentially limitless in scope. Otherwise, the Government effectively can allege a kickback payment to a pharmacist in 2005 (as it does here) and then assert that all claims submitted by that pharmacist, in perpetuity, are

"false", regardless of their underlying medical appropriateness—and perhaps even regardless of whether they are related to the product that was the subject of the kickback. The negative consequences of the Government's theory are also potentially limitless. Among other things, it would discourage discounting arrangements and adherence programs between pharmaceutical manufacturers and pharmacies—activities that benefit both patients and the government and that, to date, have not only been authorized by government agencies, but encouraged. (See infra Part II.)

To be clear, NPC is not suggesting here that a specific alleged kickback must be linked to each specific claim. Rather, NPC is arguing that the Government must plead with particularity a causal connection between the alleged kickback scheme and the medical treatment (the "items or services") included in the claims it challenges as "false", something the Government should be able to do easily if it exists considering the extensive pre-suit discovery it already has obtained from NPC. If the Government identifies a doctor whose prescriptions of Myfortic allegedly were corrupted by a specialty pharmacy that purportedly received a kickback for that purpose, then the claims associated with that doctor's Myfortic prescriptions could be considered "false claims" at the pleading stage (subject to determining, on a fully developed record, whether that is what actually happened). What the Government should not be permitted to do is identify a purported kickback to a specialty pharmacy related to Myfortic and then automatically deem all claims for Myfortic reimbursement submitted by that pharmacy "false" in perpetuity without any allegation that the pharmacist improperly influenced, or even spoke to, the relevant healthcare provider.

BACKGROUND

A. The Government's Amended Complaint.

The Government alleges that NPC engaged in two separate fraudulent schemes—one related to Exjade, and one related to Myfortic—pursuant to which it purportedly paid kickbacks to specialty pharmacies.

With respect to the Exjade scheme, the Government contends that from February 2007 to May 2012, NPC paid kickbacks to BioScrip in exchange for which BioScrip promoted Exjade by engaging in "intensive" adherence-related efforts—namely, encouraging patients to refill their Exjade prescriptions and/or resume Exjade therapy that they had discontinued. (Am. Compl. ¶¶ 144-45; see also NPC's Mem. of Law in Supp. of its Mot. to Dismiss at 3-7, February 28, 2014 (Dkt. No. 138) (summarizing in greater detail allegations of Amended Complaint).) These alleged kickbacks took the form of contractual discounts and rebates, as well as the allocation of additional patients to BioScrip through NPC's oversight of the EPASS process. (Am. Compl. ¶ 145.) The Government alleges that in February 2007, NPC "threatened" to reconsider whether BioScrip should be part of EPASS because its refill levels were below those of the other two EPASS pharmacies. According to the Government, this alleged threat transformed BioScrip's outreach calls and refill reminders into improper activity, and NPC's discounts into purported "kickbacks". The Government contends that after 2007, BioScrip used improperly trained or unqualified personnel to make calls to patients (id. ¶ 196), and obtained patient refill orders that "were not needed or clinically appropriate" (id. ¶ 194). This conduct purportedly resulted in the submission of "tens of thousands of false claims to government healthcare programs". (Id. ¶¶ 7, 231.) The Government does not identify any instance in which the alleged scheme influenced the treatment decisions of a doctor. Nor does it

identify (let alone with particularity) any patient who was convinced by BioScrip to order an Exjade refill in contravention of a doctor's orders.

With respect to the Myfortic scheme, the Government alleges that discounts and market share rebates for Myfortic in NPC's contracts with "twenty-some" pharmacies from 2005 through present constitute "kickbacks" in violation of the AKS. (Id. ¶¶ 61, 127.) The Government acknowledges that the discounts and rebates set forth in NPC's written contracts with these pharmacies are the only form of remuneration that NPC provided to the pharmacies; in other words, there were no additional or extra-contractual payments. The Government contends, however, that NPC and the specialty pharmacies entered into separate "side agreements" whereby the pharmacies supposedly committed to NPC that they would encourage doctors to "switch" patients to Myfortic from CellCept, and to "prevent" those doctors from using generic CellCept. It is these alleged "side agreements" that purportedly transformed NPC's contractual discounts and rebates into illegal kickbacks. (Id. ¶¶ 5, 64-66.) The Government alleges that these "side agreements" collectively resulted in "tens of thousands" of false claims for reimbursement, but it fails to identify a single claim for reimbursement that allegedly resulted from a pharmacy exerting improper influence over a prescribing doctor. The Government also identifies only five of the "twenty-some" specialty pharmacies to whom NPC allegedly paid kickbacks, failing to name or make particularized allegations as to the rest.

B. The AKS.

The AKS makes it illegal to offer or pay knowingly "any remuneration (including any kickback, bribe, or rebate)" to any person to induce that person to "purchase . . . order . . . or recommend purchasing . . . or ordering any good . . . or item for which payment may be made in whole or in part under a Federal health care program". 42 U.S.C. § 1320a-7b(b)(2). The

Department of Justice has described the purpose of the AKS as follows: "The Anti-Kickback Statute is intended to ensure that a physician's medical judgment is not compromised by improper financial incentives and is instead based on the best interests of the patient." See Press Release, Dep't of Justice, Pharmaceutical Company to Pay $27.6 Million to Settle Allegations Involving False Billings to Federal Health Care Programs (Mar. 11, 2014) ("DOJ Press Release"), available at www.justice.gov/opa/pr/2014/March/14-civ-251.html.

Notably, not all payments by a pharmaceutical manufacturer to a healthcare provider are prohibited by the AKS. Indeed, the first exception Congress made to the broad sweep of the AKS was for discounts and price reductions to health care providers. Pursuant to the statutory exception, the AKS:

> "[s]hall not apply to a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction of price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program".

42 U.S.C. § 1320a-7b(b)(3)(A).[1] Explaining this exception, Congress stated that the AKS "would specifically exclude the practice of discount[s] or other reductions in price from the range of financial transactions to be considered illegal under [M]edicare and [M]edicaid". H.R. Rep. No. 95-393(II), pt. 5, at 53 (1977); see also Medicare and State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952, 35,977 (July 29, 1991) (this statutory exception "is intended to cover discounts and other price reductions offered by a seller . . . to induce a buyer to order or purchase goods (including items) or services"); Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor

[1] The corresponding discount safe harbor regulation at 42 C.F.R. § 1001.952(h)(4) makes clear that a discount may take the form of a rebate.

Provision and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed Reg. 63,518, 63,526 (Nov. 19, 1999) (recognizing that discounts for health care items and services "are encouraged under the Federal health care provisions"); OIG 1994 Special Fraud Alert, 59 Fed. Reg. 65,372, 65,376 (Dec. 19, 1994) (cited by Government (Am. Compl. ¶ 18) and recognizing that statutory exceptions to AKS "protect" certain activities even if they induce drug prescriptions; note that activities addressed and condemned by alert were payments to a pharmacy each time a prescription was switched—activities that are not alleged here).

NPC raises the discount exception and safe harbor to the AKS here, because we believe it requires dismissal (either pursuant to Rule 12(b)(6) or Rule 9(b)) of the Government's Myfortic claims associated with the 15-some unidentified specialty pharmacies. As set forth above, the Government alleges that NPC gave discounts and rebates to "twenty-some" specialty pharmacies which were transformed into illegal kickbacks because of "side agreements". Yet, the Government identifies only five of the 20 pharmacies, and it is only with respect to these pharmacies that it describes the "side agreements" with any particularity. Because the alleged "side agreements" are the sole reason offered for why the challenged discounts and rebates do not come within the statutory exception, failure adequately to plead such agreements with respect to the 15 pharmacies—which, again, are not even named—should warrant dismissal of those claims. (See NPC's Mem. of Law in Supp. of its Mot. to Dismiss at 16-18, February 28, 2014 (Dkt. No. 138).) With respect to the five identified Myfortic specialty pharmacies for which "side agreements" are asserted with at least some particularity, NPC must accept those allegations as true at the pleading stage. However, NPC believes that its arrangements with those pharmacies also fall well within the statutory exception and intends to seek dismissal of these claims on that ground at the summary judgment stage to the extent they are still pending.

Similarly, while NPC must accept at the pleading stage the Government's AKS claims as to its discounts and rebates with BioScrip, it believes that its arrangement with BioScrip was at all times consistent with adherence activities that are permissible and, in fact, lauded by the government and will seek dismissal of those claims on that ground on summary judgment as well. See U.S. Dep't of Health and Human Servs., Office for Civil Rights, The HIPPA Privacy Rule and Refill Reminders and Other Communications (Sept. 19, 2013), available at http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/marketingrefillreminder.html (characterizing refill reminders as "essential healthcare communications").

In 2010, as part of the Patient Protection and Affordable Care Act, the AKS was amended to state that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]". 42 U.S.C. § 1320a-7b(g). The purpose of the 2010 amendment was to address the perceived problem that the statutory text did not clearly encompass "claims [that] are not submitted directly by the wrongdoers themselves". See 115 Cong. Rec. 25,921 (2009) (statement of Sen. Kaufman). This concern stemmed from a court decision which held that "even though a device company may have paid a kickback to a doctor to use a particular medical device, the bill to the government for the procedure to implant the device was not false or fraudulent because the claim was submitted by the innocent hospital, and not by the guilty doctor". Id. This amendment did not add a new causation requirement for an FCA action premised on a kickback claim. Rather, the 2010 amendment was merely intended to clarify that to the extent a claim "results from" a violation of the AKS, it is a false claim regardless of who submits it to the government. See id. ("amending the anti-kickback statute to ensure that all claims resulting from illegal kickbacks are 'false and fraudulent' even when the claims are not submitted directly by the wrongdoers themselves").

The key point is that the amendment was intended to capture false claims, even when submitted by a third party.

C. The FCA.

The FCA was enacted during the Civil War to prevent widespread fraud by contractors who were submitting inflated invoices and shipping faulty goods to the government. Unites States v. Rivera, 55 F.3d 703, 709 (1st Cir. 1995). The primary purpose of the FCA "is to indemnify the government—through its restitutionary penalty provisions—against losses caused by a defendant's fraud". Mikes, 274 F.3d at 696 (citing U.S. ex rel. Marcus v. Hess, 317 U.S. 537, 549, 551-52, (1943)). "The language of these [FCA] provisions plainly links the wrongful activity to the government's decision to pay." Id.

Prior to 2009, the FCA established civil liability for one who: (a) "knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), (b) "knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government," id. § 3729(a)(2), or (c) "conspires to defraud the Government by getting a false or fraudulent claim allowed or paid," id. § 3729(a)(3).

Congress amended the FCA in 2009. As amended, the three subsections now create civil liability where a defendant: (a) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," id. § 3729(a)(1)(A); (b) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," id. § 3729(a)(1)(B); or (c) "conspires to commit a violation of [another subsection of the FCA]", id. § 3729(a)(1)(C).

Not every fraud perpetrated against the government is a violation of the FCA. By the plain language of the statute, the FCA attaches liability not to underlying fraudulent activity but to the "claim for payment". See Mikes, 274 F.3d at 697 ("[W]hile the Act is 'intended to reach all types of fraud, without qualification, that might result in financial loss to the Government,' it does not encompass those instances of regulatory noncompliance that are irrelevant to the government's disbursement decisions." (citation omitted)); U.S. ex rel. Dunn v. N. Mem'l Health Care, 739 F.3d 417, 419 (8th Cir. 2014) ("The FCA is not concerned with regulatory noncompliance. Rather, it serves a more specific function, protecting the federal fisc by imposing severe penalties on those whose false or fraudulent claims cause the government to pay money. Accordingly, the FCA generally attached liability, not to the underlying fraudulent activity, but to the claim for payment." (citations and internal quotation marks omitted)).

ARGUMENT

The Government's FCA claims in this case are predicated on alleged underlying violations of the AKS. As the Court notes, the AKS does not require a kickback scheme to succeed in producing the desired result. (Novartis I at 34.) Thus, the AKS is akin to a statute prohibiting an inchoate crime, such as attempt.

But the FCA is a different statute and, when premised on an AKS violation, it is violated only where a kickback causes a healthcare provider to abandon his or her independent medical judgment when making a treatment decision. NPC submits that with respect to the two fraudulent schemes pleaded in this case—schemes where kickbacks are allegedly paid to specialty pharmacies only, and not to the physicians themselves—the only claims that can be

"false" for FCA purposes are those that were submitted due to the pharmacy exerting improper influence[2] over the doctor prescribing Myfortic or the patient refilling an Exjade prescription.

This formulation of "false claims" under the FCA is supported by the plain language and intent of the AKS and FCA, and relevant caselaw. It also prevents the over-expansive reading urged by the Government, which would, among other things, eliminate the element of causation and any particularity requirement, and result in supposed FCA violations in perpetuity by hospitals, pharmacies, pharmaceutical companies and other participants in the healthcare system, and undermine legitimate and beneficial activities engaged in by those participants—such as discounting and medical adherence programs.

I. THE GOVERNMENT MUST PLEAD THAT THE CHALLENGED CLAIMS INVOLVE PRESCRIPTIONS "RESULTING FROM" THE ALLEGEDLY FRAUDULENT SCHEMES.

A. The Plain Language of the AKS Imposes a Causation Requirement.

In the Second Circuit the "starting point in statutory interpretation is the statute's plain meaning, if it has one". United States v. Dauray, 215 F.3d 257, 260 (2d Cir. 2000). Where Congress has not defined a term, courts first consider the ordinary, common sense meaning of the words. Id. In this case, the phrase "resulting from" is not defined in the AKS, and therefore one must look at the plain meaning of the words and the statute as a whole.

[2] NPC uses the term "improper influence" because physicians and pharmacists interact routinely for various reasons, including where they discuss drug interactions, dosage levels, side effects or a patient's insurance coverage. Those types of interactions, to the extent they result in a physician selecting one medication over another based on his or her medical judgment, are clearly not the type of conduct precluded by the AKS.

According to The Oxford English Dictionary 761 (2d ed. 1989), "result" means "to arise as a consequence, effect, or conclusion from some action". See also Hemscheidt Corp. v. United States, 72 F.3d 868, 871 (Fed. Cir. 1995). Merriam-Webster's Dictionary defines "result" as "to happen because of something else that happened or was done before", or "to be caused by something else". Result, Merriam-Webster, www.merriam-webster.com/dictionary/result. These definitions make clear that applying the "ordinary, common-sense" meaning of the words "resulting from" in the context of the AKS requires causation. See Hemscheidt, 72 F.3d at 871-72. That is, for a claim to give rise to an FCA violation, the "items or services" included in the claim must "arise as a consequence of" the AKS violation.

Although NPC found no caselaw directly addressing the meaning of the phrase "resulting from" in the AKS/FCA context, in other contexts courts consistently have interpreted "resulting from" to mean causation. See Nat'l Ass'n of Mfrs. v. U.S. Dep't of Interior, 134 F.3d 1095, 1105 (D.C. Cir. 1998) (injuries that "result from" a release of a hazardous substance "require[] some causal connection between the element of damages and the injury" (citations and internal quotation marks omitted)); United States v. Hatfield, 591 F.3d 945, 948 (7th Cir. 2010) ("results from" language in a criminal statute requires at least but-for causation); Cher-D, Inc. v. Great Am. Alliance Ins. Co., No. 05 Civ. 5936, 2009 WL 943530, at *6-7 (E.D. Pa. Apr. 7, 2009) ("resulting from" contract language means proximate cause in Pennsylvania, Nevada, Texas, New York and New Jersey).

Moreover, the "resulting from" causation requirement is not limited to claims submitted after the 2010 amendment to the AKS. As discussed above (supra at 9), the 2010 amendment was unrelated to the issue of causation, meaning that the required nexus between the

alleged scheme and the substance of the challenged claim was already part of the statute. Therefore, the Government must allege the required causal nexus for all claims asserted in the Amended Complaint, both those made before and after the 2010 amendment to the AKS.

Applying that standard here, it is clear that the Government has failed to meet this FCA pleading requirement. The "items and services" included in the claims for reimbursement at issue (42 U.S.C. § 1320a-7b(g)) are prescriptions for Exjade and Myfortic. That is undisputed; there are no other items or services referenced anywhere in the Amended Complaint. The AKS violations alleged by the Government (42 U.S.C. § 1320a-7b(g)) are the supposed kickback payments NPC made to specialty pharmacies to induce the pharmacies improperly to influence doctors to prescribe Myfortic and patients to order Exjade refills. That too is undisputed; the Government does not point to any other purported AKS violation, nor does it allege that NPC made kickback payments to any physician or Exjade patient. Accordingly, in order to plead that the "items and services" (Myfortic and Exjade prescriptions) included in the claims for reimbursement at issue "resulted from"/arose as a "consequence" of/or "happened because of" the purported AKS violation (kickback payments to pharmacies), the Government must allege that the pharmacies caused doctors to write Myfortic prescriptions that they otherwise would not have written, and caused patients to order Exjade refills (in contravention of a doctor's instruction) that they otherwise would not have ordered. We submit there simply is no other way for the Government properly to plead an FCA claim based on the type of underlying AKS violation it asserts here—that is, one where the alleged kickbacks are paid not to the prescribing physicians, but to the pharmacists that dispense the prescriptions. Merely alleging a kickback payment to a specialty pharmacy in connection with Myfortic or Exjade, and then characterizing all subsequent Myfortic and Exjade claims submitted by the pharmacy for

reimbursement as "legally false" because the pharmacy was in receipt of a kickback ignores entirely the "items and services resulting from" language. Put another way, where the "items and services" that are the subject of the reimbursement claim are the product of a physician's untainted and independent medical judgment, they did not "result from" an AKS violation and cannot be considered false claims for purposes of the FCA.

NPC submits that this reading of the AKS does not significantly restrict the definition of legal falsity in the FCA context. (Novartis I at 43.) Falsity and causation are distinct requirements, both of which the Government must plead. For example, even where causation properly is established—in other words, there are sufficient allegations that a kickback caused a doctor to write a prescription—the Government still needs to establish a false claim.[3] Although falsity (whether legal or factual) is usually a follow-on to causation, there could be a situation where the claim is never submitted for reimbursement or where the doctor discloses in the certification that he or she was influenced by a financial incentive. In fact, as set forth above, the Congressional Record reflects that the 2010 amendment to the AKS was prompted by a case where the court found there was causation under the FCA (a doctor was paid a kickback to purchase a medical device) but no falsity (because the device reimbursement claim was

[3] Defendants Accredo Health Group and Curascript, Inc. have separately moved to dismiss the Relator's Amended Complaint under Rule 12(b)(6) on the grounds (among others) that the Relator has not adequately pleaded false certifications as required under controlling Second Circuit precedent. See Mikes, 274 F.3d 687. NPC will not repeat those arguments here but joins in the certification arguments advanced by Accredo and Curascript, which apply with equal force to the Government's claims. Notably, the certifications upon which the Government relies (Am. Compl. ¶ 23) themselves imply a causal nexus by referring to payments "conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions". CMS Form-855S (04/06) at 26 (emphasis added).

submitted by an unrelated third party). See 115 Cong. Rec. 25,921 (2009). The AKS was amended to make clear that there was also falsity in this circumstance, not just causation.

The concepts of causation and falsity are often conflated where the person who receives the kickback and the person who writes the prescription at issue are the same, which is virtually always the allegation. (See infra Part I.C.) Here, however, there is a distinction between the person receiving the alleged kickback (the pharmacist) and the person writing the prescription for the items and services underlying the claim (the doctor). NPC is merely arguing that to meet the "resulting from" requirement, the Government must plead that (i) as to Myfortic, the prescribing physician was improperly influenced by the pharmacist who received the purported kickback to prescribe Myfortic in a way that was not clinically appropriate; and (ii) as to Exjade, the patient ordering a refill was somehow influenced by the pharmacist to order a refill that was "not needed or clinically appropriate" despite the existence of a valid prescription.

B. A Causation Requirement is Consistent with the Purpose of the AKS and FCA.

As set forth above, the Government itself has recognized that the AKS "is intended to ensure that a physician's medical judgment is not compromised by improper financial incentives and is instead based on the best interests of the patient". See DOJ Press Release; see also U.S. ex rel. Westmoreland v. Amgen, Inc., 812 F. Supp. 2d 39, 53 (D. Mass. 2011) ("Kickbacks are designed to influence providers' independent medical judgment in a way that is fundamentally at odds with the functioning of the system as a whole. The Anti-Kickback Statute is intended not only to prohibit but also to prevent such fraudulent conduct.").

The FCA was enacted to prevent fraud by Civil War-era contractors who were presenting the government with inflated invoices and faulty goods. See Rivera, 55 F.3d at 709; see also Vt. Agency of Natural Res. v. U.S. ex. rel. Stevens, 529 U.S. 765, 781 (2000) (FCA

"was enacted in 1863 with the principal goal of stopping massive frauds perpetrated by large [private] contractors during the Civil War" (internal quotation marks omitted) (brackets in original)); U.S. ex rel. Colucci v. Beth Israel Med. Ctr., 785 F. Supp. 2d 303, 310 (S.D.N.Y. 2011) (a claim is false or fraudulent if it "is aimed at extracting money the Government otherwise would not have paid" (internal quotation marks omitted)); 31 U.S.C. § 3729(a) (FCA damages are those "which the Government sustains because of the act of [the defendant]").

Taken together, which must be done here where the Government alleges an FCA violation based on an AKS violation, these statutes are aimed at prohibiting the use of financial incentives to compromise a healthcare provider's independent medical judgment and protecting the government from any monetary losses resulting from that compromised judgment—an aim that is entirely consistent with the requirement that there be a causal nexus between an alleged kickback to a healthcare provider and the items that are the subject of the claim for reimbursement submitted by that provider.

Pursuant to the Government's theory, even if a Myfortic prescription was written by a doctor solely based on the doctor's independent medical judgment—and the doctor never received a kickback herself, nor did she speak with anyone at the specialty pharmacy who allegedly received a kickback—the claim for reimbursement of that Myfortic prescription would still give rise to an FCA claim. But under this scenario, the doctor's independent medical judgment has not been compromised, nor has the government suffered any "loss" as a result. See OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731-01, 23,734 (May 5, 2003) (recognizing that where a potential inducement fails to "interfere with, or skew, clinical decision-making" such activities may not implicate the AKS). In contrast, where a "but for" nexus is properly pleaded, the combined goals of the statute are met: there is an

alleged kickback that compromises a doctor's medical judgment such that the resulting claim to the government for an item or service is fraudulent to the government's detriment.

C. Caselaw is Consistent with the Requirement of a Causal Link.

The Government's theory—that a claim is false regardless of whether a kickback had any alleged effect on a physician's treatment decision—represents a dramatic departure from prior enforcement actions, virtually all of which involved a link between payment of the kickback (usually directly to a physician) and the challenged claim for reimbursement. See, e.g., U.S. ex rel. Nunnally v. West Calcasieu Cameron Hosp., 519 Fed. Appx. 890 (5th Cir. 2013) (alleging that hospital submitted false claims by charging reduced test fee to physicians in return for the physicians referring all patients in need of laboratory tests to the hospital); U.S. ex rel. Hutcheson v. Blackstone Med., Inc., 647 F.3d 377 (1st Cir. 2011) (alleging that defendant paid kickbacks to physicians that induced physicians to use defendant's medical devices and caused hospitals and physicians to submit false claims to Medicare); U.S. ex rel. Poteet v. Medtronic, Inc., 552 F.3d 503 (6th Cir. 2009) (alleging that medical technology manufacturer violated FCA by paying illegal kickbacks to physician customers in exchange for their business); Hericks v. Lincare Inc., No. 07 Civ. 387, 2014 WL 1225660 (E.D. Pa. Mar. 25, 2014) (alleging that defendant paid kickbacks to doctors in violation of the FCA); U.S. ex rel. Moore v. GlaxoSmithKline, LLC, No. 06 Civ. 6047, 2013 WL 6085125 (E.D.N.Y. Oct. 18, 2013) (Novartis I at 16) (alleging that defendant induced physicians, through a purported kickback scheme, to issue prescriptions for certain HIV medications manufactured by defendant); U.S. ex rel. Kennedy v. Aventis Pharm., Inc., 610 F. Supp. 2d 938 (N.D. Ill. 2009) (Novartis I at 41) (alleging that Aventis aggressively made payments to hospitals and a pharmacist, who was a member of the hospital's formulary committee, to encourage them to prescribe an Aventis drug);

U.S. ex rel. Repko v. Guthrie Clinic, P.C., 557 F. Supp. 2d 522 (M.D. Pa. 2008) (Novartis I at 38) (alleging that in exchange for favorable financial agreements, defendant clinic and its physicians would refer large volumes of patients to defendant hospital); U.S. ex rel. Pogue v. Diabetes Treatment Ctrs. of Am., Inc., 238 F. Supp. 2d 258 (D.D.C. 2002) (alleging that illegal kickbacks were paid to physicians in exchange for patient referrals to diabetes treatment centers); U.S. ex rel. Pogue v. Am. Healthcorp Inc., 914 F. Supp. 1507 (M.D. Tenn. 1996) (Novartis I at 41) (alleging that in return for kickbacks, individual physicians would refer their Medicare and Medicaid patients to defendant medical center for treatment).

Each of the cases cited by the Government involving an FCA claim premised on an AKS violation similarly includes alleged improper conduct by a physician, or at least some physician involvement, most typically that the physician himself or herself received a kickback. See U.S. ex rel. Wilkins v. United Health Grp., 659 F.3d 295 (3d Cir. 2011) (03/21/14 Letter from Preet Bharara to Hon. Colleen McMahon ("Gov't Letter") at 6; Novartis I at 31) (alleging that defendant violated the FCA, in part, by paying doctors to provide the names of patients eligible for Medicare and Medicaid programs); New York v. Amgen, 652 F.3d 103 (1st Cir. 2011) (Gov't Letter at 2; Novartis I at 32) (alleging that defendant employed a kickback scheme to induce medical providers to prescribe one of its drugs); United States v. Rogan, 517 F.3d 449 (7th Cir. 2008) (Gov't Letter at 6; Novartis I at 41) (alleging that defendant paid physicians in order to induce patient referrals to Edgewater Medical Center); U.S. ex rel. Schmidt v. Zimmer, Inc., 386 F.3d 235 (3d Cir. 2004) (Gov't Letter at 6; Novartis I at 41) (alleging that defendant violated the FCA, in part, by paying physicians and orthopedic departments to use particular orthopedic implants); U.S. ex rel. Parikh v. Citizens Med. Ctr., 977 F. Supp. 2d 654 (S.D. Tex. 2013) (Gov't Letter at 4; Novartis I at 34) (alleging that hospital paid bonuses to physicians in

order to induce them to refer patients for cardiology treatment at Citizens Medical Center); U.S. ex rel. Freedman v. Suarez-Hoyos, No. 04 Civ. 933, 2012 WL 4344199 (M.D. Fla. Sept. 21, 2012) (Gov't Letter at 2) (alleging existence of a kickback scheme in which a clinical laboratory allowed a dermatologist to bill Medicare for work that he did not do in exchange for the doctor sending more biopsy specimens to the lab); Westmoreland, 812 F. Supp. 2d 39 (Gov't Letter at 5-6; Novartis I at 42 n.8) (alleging that defendant violated the FCA, in part, by providing medical providers with kickbacks in the form of "excess overfill[s]" in order to encourage them to prescribe an Amgen drug); U.S. ex rel. Fry v. Health Alliance of Greater Cincinnati, No. 03 Civ. 167, 2008 WL 5282139 (S.D. Ohio Dec. 18, 2008) (Gov't Letter at 5) (alleging an FCA violation as a result of defendants assigning time to cardiologists in the hospital's heart station in proportion to the volume of referral of cardiac procedures made by cardiologists to the hospital).

(All other cases cited to by the Government are either outside the healthcare context or involve FCA claims that are not based on an underlying AKS violation. See, e.g., U.S. ex rel. Feldman v. Van Gorp, 697 F.3d 78 (2d Cir. 2012) (Gov't Letter at 6) (false statements regarding research training grant application); U.S. ex rel. Ge v. Takeda Pharm. Co., 737 F.3d 116 (1st Cir. 2013) (Gov't Letter at 5 n.6) (failure to disclose adequately potential side effects of drugs); U.S. ex rel. Grubbs v. Kanneganti, 565 F.3d 180 (5th Cir. 2009) (Gov't Letter at 4) (claims for psychiatry services not performed).)

Contrary to these cases, the Government's theory completely removes doctors and their prescribing decisions from the operative facts upon which its FCA claims are premised. NPC has found no case in which a court permitted FCA claims to proceed on such a novel and sweeping theory. Notably, in the context of FCA violations based upon claims of off-label promotion, the Second Circuit has held that a class action for off-label promotion could not be

sustained where the plaintiff did not show that the decisions by individual doctors to prescribe a drug were affected by the unlawful marketing scheme. See UFCW Local 1776 v. Eli Lilly & Co., 620 F.3d 121, 136 (2d Cir. 2010) ("Plaintiffs cannot use generalized proof when individual physicians prescribing Zyprexa may have relied on Lilly's alleged misrepresentations to different degrees, or not at all . . . ."). Admittedly the Second Circuit has not addressed this same issue in the AKS context, but its reasoning in the Eli Lilly case suggests that it would require an allegation that an individual doctor "relied on" the improper recommendations of pharmacists when writing a Myfortic prescription.

II. THE GOVERNMENT'S THEORY OF FALSITY IS OVERBROAD.

The absence of a requirement that the Government allege a causal link between the alleged kickback and the submission of a claim would transform the potential scope of this case and all future FCA cases asserted by the Government or private relators. Prescriptions written by a doctor exercising his or her independent medical judgment based upon the best interests of the patient—a doctor who had not only never received any alleged "kickback" but also one who had never interacted with a pharmacist—would be rendered "false". There also would be no limit on the taint. If a Myfortic kickback were paid to a pharmacist in year one, under the Government's theory all Myfortic claims submitted by the pharmacy in perpetuity are arguably false; there is no temporal boundary. It is also not difficult to imagine the Government or private relators taking the position that a kickback related to some subset of claims for a particular drug "taints" all claims submitted by the specialty pharmacy for the entire portfolio of the drug manufacturer, regardless of whether there were any allegations that the alleged kickbacks related to those other drugs.

The FCA was never intended to, and should not, reach the scenarios above. A requirement that the items included in the claim submitted for reimbursement "result from" the alleged fraudulent scheme is a far more reasonable approach, which circumscribes FCA claims in a manner consistent with the statute's plain language and purpose.

It also is an approach that does not impose an undue pleading burden on the Government, particularly here, where the Government investigated these issues pursuant to its subpoena power for nearly two years. At the time it filed its Amended Complaint, the Government had full details on all claims for Myfortic and Exjade that it paid, including the names of the prescribers and medical histories of the patients treated. It also had millions of pages of documents from NPC, documents from pharmacies and hospitals, and the ability to take an investigative deposition of anyone—including doctors—with relevant information. In light of this information and access, the Government should be well aware of any causal link between the alleged kickbacks to the pharmacists and the prescriptions for Myfortic and Exjade that are the subject of the claims it now challenges. And if those causal links in fact exist, the Government should be required to plead them consistent with standards set forth in the FCA and Rules 12(b)(6) and 9(b).

CONCLUSION

For the foregoing reasons, the Court should grant NPC's motion to dismiss the Amended Complaint in Intervention of the United States.

Dated: June 13, 2014

Respectfully submitted,

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